

Remarks

This is a full and timely response to the Office Action of September 22, 2008. Reconsideration and allowance of the application and all presently pending claims are respectfully requested.

Claims 1, 3, 5, 6, 14 to 27, and 29 to 31 are pending in this application. Claims 2, 4, 7 to 13 and 28 have been cancelled without prejudice. Claims 1, 3, 14, 16, 18, 23, and 26 are currently amended. Claim 1 has been amended to include the features of claim 2 and to remove reference to the last phrase. Claim 18 has been amended to include an additional cancer, support for which is found at page 28 of the specification. New claims 29 to 31 have been added to more fully claim embodiments of the invention disclosed in the specification as originally filed. The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims. Applicants believe that no new matter has been added by the amendments and that a new search is not necessary.

Information Disclosure Statement

The Office Action has stated that the Information Disclosure Statement (IDS) submitted on December 5, 2005 did not include publication dates. A revised IDS, including the publication dates, is enclosed.

Claim Rejections

35 U.S.C. §112, first paragraph

Claims 7 to 11 and 14 to 22 were rejected under 35 U.S.C. 112, first paragraph. As claims 7-11 have been cancelled, only claims 14-22 remain rejected.

The Office Action asserts that the specification only enables treating breast cancer, but not cancer involving inappropriate tyrosine-kinase activity.

Particularly, at p. 3, the Office Action asserts claims 14-22 are 'reach through' claims, which "include[] 'treatment of all types of cancer'." The Office Action bases this misinterpretation of claim 14 because p. 27 of the Specification recites, "In summary, the compounds of the invention have been shown to be useful in the treatment of a variety of cancers." Applicants respectfully assert the Office Action disregards the rule

of law in asserting that claim 14 encompasses treatment of all types of cancers for the following reasons:

In order to conclude claim 14 is drawn to treating all cancers, the preamble of claim 14 must be ignored. The preamble of claim 14 reads:

"14. A method for treatment of cancer *involving inappropriate tyrosine kinase activity* in a mammal in need of such treatment, said method comprising. . ."

(Emphasis added)

As emphasized, claim 14 clearly delineates the type of cancers sought to be treated, and the Office Action completely ignores the emphasized language. Otherwise, it is simply impossible to conclude claim 14 encompasses treatment of every known cancer. In light of the fact that the preamble of claim 14 specifically limits "cancer" to those involving "inappropriate kinase activity", it is difficult to understand how or why this clause is ignored.

Ignoring the preamble of a claim is not the subjective choice granted to an Examiner while interpreting claims in the examination process. MPEP 2111.02.

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life meaning, and vitality' to the claim, the the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes v. Hewlett-Packard*, 182 F.3d 1298, 1305; 51 USPQ2d 1154, 1158 (Fed. Cir. 2003).

The portion of the preamble ignored provides a limitation to the scope of the cancers sought to be treated. Had Applicants intended to claim treatment of all cancers, there would be no need to include reference to those "involving inappropriate kinase activity". Such a limitation cannot be ignored because it is essential to explicitly define the metes and bounds of claim 14.

The Office Action uses the Specification as support to conclude claim 14 is drawn to treating all types of cancers:

"The specification at page 27 recites that 'the compounds of the invention are useful in the treatment of a variety of cancers'. As provided by the specification, the scope of therapeutic method encompassed by the instant claims includes

'treatment of all types of cancer'. The instant claims cover 'cancer disorders' that are known to exist and those that may be discovered in the future, for which there is no enablement." p. 3.

With this statement, the Office Action errs in at least three ways.

First, the Office Action relies on the Specification rather than the claims to define the invention. It is the claims and not the Specification which determine whether an invention is patentable. According to 35 USC 112, second paragraph, it is the claims, not the Specification, which must, "set forth the subject matter that applicant regards as their invention; and the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant." Also, limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs v. 3Com*, 343 F.3d 1364, 1369; 67 USPQ2d 1947, 1950 (Fed. Cir. 2003). In this case, the Office Action interprets a statement from the Specification as if it were included in claim 14. However, it is impermissible to import limitations recited in the Specification into the claims.

Second, the statement at p. 27 of the Specification is read out of context. Read in context of the entire Specification, any skilled artisan would realize the summary statement at p. 27 cited by the Office Action refers to a variety of cancers associated with inappropriate tyrosine kinase activity.

Third, the Office Action alleges claim 14 covers all cancer disorders "known to exist and those that may be discovered in the future". Applicants respectfully disagree. Claims are interpreted in light of what is known in the art at the time of the invention. They are not interpreted based on what might be known in the future.

The arguments put forth in the Office Action are based not only on an erroneous interpretation of claim 14 but also on an overreaching interpretation of 35 USC 112, first paragraph. The Office Action alleges that the breadth of claim 14 is not supported by the information contained within Specification, because there is no "silver bullet" capable of "treat[ing] proliferative disorders or cancers of all types generally." p. 4. Essentially, the Office Action interprets enablement as requiring proof that the compounds of formula (I) are capable of treating every cancer.

However, the question to be answered in an enablement analysis is not whether a claimed compound could treat every known cancer. The scope of enablement must

only bear a reasonable correlation to the scope of the claims. MPEP 2164.08; *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) (Emphasis added).

Applicants respectfully submit that the cancers associated with inappropriate tyrosine kinase activity bear a direct and reasonable correlation to the assay data provided in the Specification and in the Declaration (submitted herewith). At a minimum, the *in vitro* and *in silico* data presented in the Specification and Declaration shows a reasonable correlation to treating cancers associated with inappropriate tyrosine kinase activity.

Test assays and procedures using certain cancer cell lines are provided at pages 27 to 29 of the Specification. The *in silico* data found in Table 1 on page 28 of the description clearly predicts that compounds of Formula I, particularly the compound designated COTI-001, are effective at inhibiting the growth of a variety of cancer cells of different origin, including leukemias, lung cancers, colon cancers, CNS cancers, melanomas, ovarian cancers, renal cancers, prostate cancers, and breast cancers. In addition, a Declaration is enclosed showing further evidence of enablement for such cancers.

The enclosed Declaration also demonstrates evidence of enablement for a method of treating cancer involving inappropriate tyrosine kinase activity, in conjunction with the data already provided at pages 27 to 29 of the specification, for example, showing that the compounds are useful in the treatment of a variety of cancers, including leukemias, lung cancers, colon cancers, CNS cancers, melanomas, ovarian cancers, renal cancers, prostate cancers, and breast cancers.

The Office Action also asserts that there is no disclosure regarding how the patient in need of such specific inappropriate kinase activity is identified and further, how types of cancer are treated. Applicant disagrees. Administration is clearly described at, for example, pages 25 to 27 of the specification. With respect to the identification of the patient in need of such treatment, the cancers claimed are known to be tyrosine kinase dependent cancers (see the background of the invention) and patients diagnosed with such cancers would therefore be understood by persons skilled in the art to be in need of a compound that is effective in treating cancers characterized by inappropriate tyrosine kinase activity.

For the aforementioned reasons, Applicants respectfully assert that the Specification enables a skilled artisan to treat cancers associated with inappropriate tyrosine kinase activity, as recited in claim 14.

35 U.S.C. §112, second paragraph

Claims 23 to 28 are rejected under 35 U.S.C. 112, second paragraph.

The Office Action asserts that claim 23 is improperly dependent. Claim 23 has been amended to be properly dependent.

The Office Action also asserts that claim 26 is not clear with respect to “and mixtures thereof”. Claims 1, 14, 16, and 26 have been amended to clarify language.

The Office Action also asserts that claim 28 is not properly dependent upon claim 26. Claim 28 has been cancelled without prejudice.

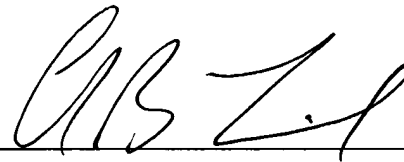
CONCLUSION

In light of the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Furthermore, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known since the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'CBL', is written over a horizontal line.

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